UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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Subject: Clothianidin Emergency Citizen Petition dated March 20, 2012

Dear Mr. Jenkins:

This letter constitutes the U.S. Environmental Protection Agency's (EPA or Agency) partial response to the petition dated March 20, 2012, (Petition) that you submitted on behalf of 27 petitioners seeking the suspension of registrations for the insecticide clothianidin. The petition specifically requests the agency to take four steps: (1) cure clothianidin's allegedly unlawful conditional registration; (2) prevent alleged imminent harm by suspending clothianidin's registrations and initiating special review and cancellation proceedings; (3) suspend and stop sale of allegedly misbranded clothianidin products; and (4) address Endangered Species Act consultation obligations for clothianidin.

This partial response addresses only the petitioners' request that the EPA suspend clothianidin registrations to prevent imminent harm. Given the emergency nature of that request and the harm alleged, the EPA believes it is appropriate to address that request on an expedited basis without requesting public comment on the emergency claims. The EPA is posting this response for public comment on its website along with the petition (including the petition exhibits and supplemental filings). After reviewing the public comments submitted in connection with this response and the EPA's posting of the petition, the EPA will respond to the remaining issues in the petition. In addition, the EPA will determine in connection with that review whether the comments received support the reconsideration of this partial response.

Petitioners make the following assertions in support of their belief that an imminent hazard exists:

(1) Research indicates that honey bee colonies are in decline recently and it appears to correlate with registration of clothianidin and the neonicotinoid pesticides.

(2) The weight of the science on both neonicotinoids generally and clothianidin in particular shows that exposure to harmful amounts of clothianidin is a likely factor in this abnormal decline of honey bees. In particular, petitioners make the following assertions about clothianidin exposure and toxicity as it relates to bees and other pollinators to support the request that the EPA take action to remove clothianidin from the market:

a. Circumstances giving rise to high clothianidin exposures are widespread because the pesticide is very widely used and persistent; dusts from seed treatments can expose bees regularly to harmful amounts of clothianidin; and given the systemic nature of clothianidin, bees are also regularly exposed to clothianidin from visiting plants and trees.
b. These exposures to clothianidin can and do cause harm because it has lethal effects on honey bees; it has effects on honey bee behavior and cognition in ways that compromise the overall health of colonies, consistent with losses seen from colony collapse disorder (CCD); and it has interactive/synergistic effects with pathogens and disrupts bees' microbial communities.
c. Incident data support these assertions.

(3) After 9 years of clothianidin use and what appear to be correlated, abnormal die offs of honey bee populations, the evidence suggests that harm to bees from clothianidin could cause the collapse of bee populations resulting in agricultural losses in the tens of billions of dollars and irreparable ecological damage.

Since receipt of the petition, the EPA has received multiple submissions of supplemental filings and additional materials from other sources. All of these materials are available in the public docket and will be considered in the EPA's response to the complete petition. In this partial response, the EPA is presenting its review only of materials received prior to May 4, 2012, due to the emergency nature of this request.[1]

The first section of this response discusses clothianidin's regulatory history and background. The second section discusses the applicable statutory framework. The third section sets out the EPA's assessment of petitioners' arguments as to why clothianidin registration should be suspended to prevent an imminent hazard. That section addresses the allegations in the petition in detail by addressing separately assertions regarding bee exposure and toxicity. It also includes a discussion of bee-related clothianidin adverse incidents. The final section is the EPA's conclusion regarding the imminent hazard of clothianidin. The EPA has included its Technical Support Document for this response as an attachment.

I. Clothianidin Regulatory History and Background

Clothianidin is a neonicotinoid insecticide registered by the EPA under section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the federal law that requires the registration of pesticides. Neonicotinoid pesticides are a class of pesticides related to nicotine that are effective against a wide variety of insect pests (e.g., piercing sucking insects and chewing insects) and widely recognized as alternatives to the organophosphate insecticides. Neonicotinoid pesticides are also systemic, which means that the pesticides are taken up by the plant either through their roots or the surface of the plant. Systemic pesticides used as seed treatments effectively protect the early life stages of the growing plant. The EPA originally evaluated the clothianidin application jointly with Canada under the North American Free Trade Agreement (NAFTA) Joint Review program.

In 2003, the EPA granted Bayer CropScience (Bayer) the original registration of clothianidin for use as a corn (field, sweet, and pop) and canola seed treatment to protect against early season pests: soil and leaf pests like aphids, beet leaf miners, black cutworms, corn rootworms, flea beetles, grubs,

[1] As EPA counsel has discussed with you, the Agency concluded that it could not meet the expedited response period sought by the petitioners unless it established a reasonable cut-off date for the record that allowed us to appropriately review and consider record materials before responding.

leafhoppers and wireworms. The EPA approved conditionally the 2003 registration of clothianidin. Among other things, the EPA required Bayer to submit data from studies testing the effects of clothianidin on pollinators in the field.

In August of 2007, Bayer submitted a field test for pollinators to the EPA. This study was reviewed and found to be acceptable in November 2007 and the data requirement for the field test pollinator study was considered to be fulfilled at that time[2]. Since all of the initial conditional data requirements had been met, on April 22, 2010, the EPA notified Bayer of the unconditional status of its registration.

In recent years, questions have been raised regarding the possible connection between the registration and use of neonicotinoid pesticides and declines in bee and other pollinator populations – including possible connections with CCD. As a result, the EPA has been working with the United States Department of Agriculture (USDA) to integrate the evaluation and management of potential risks from pesticides with other factors (e.g., poor nutrition and disease) associated with pollinator declines into a coordinated government-level response to pollinator declines. The EPA is a member of the USDA-led CCD Steering Committee. The EPA tracks national research efforts funded through the USDA to examine the various factors associated with pollinator declines. The EPA has collaborated with the USDA and the University of Maryland on research examining exposure and effects of the neonicotinoid insecticide, imidacloprid, providing technical and analytical support. Additionally, the EPA has contributed to advancing the methodology to detect pesticide residues at low levels. These efforts have improved research abilities to understand potential exposure of bees (particularly residues of neonicotinoids and their metabolites) in matrices where researchers have historically had limited and/or no detection capabilities (*e.g.*, pollen and comb wax). The EPA has conducted preliminary reviews of more recent open literature regarding the effects of neonicotinoid insecticides on pollinator health and acknowledges that there is a significant challenge in understanding the complex relationship between pesticides and effects to honey bees as well as other environmental factors in terms of characterizing and interpreting the potential for sublethal effects.

The EPA also participated in a global SETAC (Society of Environmental Toxicology and Chemistry) Pellston Workshop from January 16 to 21, 2011. The Executive Summary of the Workshop was published on-line by SETAC in August of 2011; the final product, a book published by SETAC, is expected to be released in late 2012. Key recommendations of the Workshop included: 1) a state-of-the science, global process for consistently quantifying risks to honey bees and non-*Apis* bees from pesticides; 2) recommendations for exposure and effect data needed to inform the risk assessment process; and 3) guidance on consistent statistical analysis and interpretation of lab and field studies.

The EPA also is closely working with the California Department of Pesticide Regulation (DPR), the USDA, Health Canada's Pesticide Management Regulatory Agency (PMRA), and registrants to establish study protocols relevant for bee risk assessment. Based on its interactions with the other regulatory agencies and research institutions both nationally and internationally, in September 2012, the EPA will present its proposed, new process for quantifying risk to insect pollinators at the FIFRA Scientific Advisory Panel (SAP) reflecting the current state of the science for assessing risks to insect pollinators. Both PMRA and DPR will be collaborating with the EPA on its presentation to the FIFRA

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[2] In December of 2010, the EPA reclassified Bayer's field test for pollinators as Supplemental. A study that has been classified as supplemental has the potential to be upgraded to acceptable if the submitter can provide missing data or information to further clarify the study. This reclassification of the assessment is reflective of the EPA's improved understanding of honey bee biology and the recognition in the scientific community of the challenges associated with field pollinator study designs.

SAP. The EPA has also enhanced ways that pollinator losses can be reported to the Agency: 1) National Pesticide Information Center (http://npic.orst.edu/); 2) the EPA's beekill@epa.gov; and 3) direct phone links. It is our intention to use the results of the SAP and our extensive work with our regulatory partners to inform the further evaluation of the regulatory status of clothianidin and the neonicotinoids in general.

In addition to participating in interagency meetings concerning pollinators, in December of 2011 the EPA initiated the Registration Review process for clothianidin. The registration review program makes sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no "unreasonable adverse effects on the environment." The EPA initiates a registration review by establishing a docket for a pesticide registration review case and opening the docket for public review and comment. Each docket contains information on what the agency knows about the pesticide and describes the EPA's thought process for determining the anticipated data and assessment needs. In the clothianidin case, the EPA signed the Final Work Plan for the Registration Review for clothianidin on June 19, 2012. This document is available, along with responses to comments received on the Preliminary Work Plan, in the public docket (Docket Number EPA-HQ-OPP-2011-0865).

II. Statutory Background

Subject to limited exceptions, a pesticide may be distributed or sold in the United States only if it is registered by the EPA under FIFRA. 7 U.S.C. § 136a(a). Under FIFRA, the EPA must register a pesticide if, among other things, the pesticide, when used in accordance with widespread and commonly recognized practice, generally will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). Section 2(bb) defines "unreasonable adverse effects on the environment" as, among other things, "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide . . . ." 7 U.S.C. § 136(bb). This portion of the unreasonable adverse effects standard creates a "risk-benefit" standard wherein the EPA compares the risks presented from the use of a pesticide with the benefits to society from the use of the pesticide. Once a pesticide is registered, the EPA must periodically review that pesticide registration. 7 U.S.C. §§ 136a(g), 136a-1. If the EPA determines at any time that a registered pesticide, including its approved labeling, no longer meets the standard for registration, the EPA may initiate cancellation proceedings. 7 U.S.C. § 136d(b).

The EPA may commence proceedings to suspend the registration of a pesticide during the period necessary to complete cancellation proceedings if it determines that an "imminent hazard" exists from the use of the pesticide. 7 U.S.C. § 136d (c). Section 2(l) of FIFRA defines imminent hazard as,

> [A] situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act . . . .

If the EPA determines that an emergency exists such that the imminent hazard will occur during the period necessary to complete normal suspension proceedings, the EPA may issue an immediately effective emergency suspension order in advance of completing suspension proceedings. 7 U.S.C. § 136d(c)(3).

Courts addressing the suspension provisions have held that an imminent hazard exists if there is "a substantial likelihood that serious harm will be experienced during the year or two required in any realistic projection of the administrative process." *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988)

(quoting *Environmental Defense Fund v. EPA*, 465 F.2d 528, 540 (D.C. Cir 1972). In the case of an emergency suspension, one court has found by analogy that suspension is appropriate if there "a substantial likelihood that serious harm will be experienced during the three or four months required in any realistic projection of the administrative suspension process." *Dow v. Blum*, 469 F.Supp. 892, 901 (E.D.Mich. 1979). Thus, the courts interpreting the FIFRA suspension standard have made clear that an imminent hazard finding requires a greater degree of likelihood, immediacy and severity of harm than is otherwise required to take cancellation action under FIFRA. And in evaluating the nature and extent of information before the agency, the courts have instructed the EPA to consider (1) the seriousness of the threatened harm; (2) the immediacy of the threatened harm; (3) the probability that the threatened harm will occur; and (4) the benefits to the public of the continued use of the pesticide. *Id.* at 902. In this response to imminent hazard allegations, the EPA is considering each of these factors.

It is important to note that the absence of data is generally not sufficient for the agency to determine that an imminent hazard exists.

III. Petition Response

A. *Summary*

For the reasons set forth below, the EPA denies the petition insofar as petitioners seek to have the EPA make a finding that the use of products containing clothianidin presents an "imminent hazard," as defined in FIFRA section 2(l), and should be suspended under section 6(c) of FIFRA.
The EPA considers this portion of the response to the petition to be final action pursuant to section 16 of FIFRA. As noted above, the EPA will respond to the remainder of the petition following the receipt and review of any comments received on the petition and on this response. The EPA will also review the comments received and consider whether they support the reconsideration of this response.

In general, petitioners assert that clothianidin presents an "imminent hazard" based on the assertions of harm outlined above and on the assertion that such harm may result in economic losses from the collapse of bees that measure in the tens of billions of dollars and that the ecological impacts of lost pollinators would be irreparable. And petitioners attempt to back up these claims by citing to research in the public literature and incident reports that allegedly establish the potential for such impacts. However, nowhere in the petition do petitioners explain how the use of clothianidin rises to the level of the FIFRA imminent hazard standard.

When asking the agency to suspend a pesticide because of an "imminent hazard", the EPA believes the petition must, at a minimum, make a showing that an imminent hazard exists and that petitioners are therefore entitled to relief. As set forth in the legal background section of this response, and as explained by the federal courts, the imminent hazard standard includes the concept that the harm is imminent; that is, that it must be occurring or likely to occur within the one to two years necessary to complete cancellation proceedings – or in the case of an emergency suspension, within the three to four months necessary to complete suspension proceedings. However, nowhere in the petition do the petitioners explain whether the serious agriculture and ecological harm alleged on page 36 of the petition is likely to occur during these time periods. Further, the imminent hazard standard also incorporates FIFRA's unreasonable adverse effects standard, which is a "risk-benefit" standard. Because petitioners only address the potential harm from the use of clothianidin without addressing whether that harm is unreasonable when weighed against clothianidin's benefits, the petition also fails to address this threshold matter as well. Absent any discussion regarding the immediacy of the harm alleged or an explanation as to how the harm identified outweighs the benefits to growers and the agricultural

economy from the use of the pesticide, the petition fails to make a showing of imminent hazard and is therefore denied on that basis.

Despite the facial inadequacy of petitioners' imminent hazard claim, given the nature of the harm asserted, the EPA examined the evidence cited by petitioners to determine whether that information demonstrates that there is nonetheless a substantial likelihood of serious imminent harm. Based on the data, literature, and incidents cited in the petition and otherwise available to the Office of Pesticide Programs, the EPA does not find there currently is evidence adequate to demonstrate an imminent and substantial likelihood of serious harm occurring to bees and other pollinators from the use of clothianidin. The data, literature and incident reports do make clear that clothianidin is acutely toxic to bees, and that adverse effects to foraging bees occasionally occurs as the result of clothianidin use. However, absent information that adverse effects to pollinators are causing or will, in the next year or two, cause reductions in populations of managed bees or native pollinators that could result in serious economic or ecological damage (such as significant decreases in honey production, wide-scale impacts on agricultural production as a result of decrease in pollination services, or a reduction in the pollination of wild plants in a way that may alter ecosystems), the EPA believes that there is insufficient information to support an imminent hazard finding. And the petition does not include evidence of population declines or colony losses associated with clothianidin that are causing or could cause these types of impacts. The EPA regards the occurrences of the incidents of bee kills resulting from pesticides as a plainly undesirable risk and, as stated above, continues to work with our partners to investigate the causes of adverse effects to pollinators. And the agency is not ruling today on the petitioners' request that clothianidin registrations be cancelled. However, neither the data nor the incidents suggest that substantial likelihood of serious, imminent harm exists from the current use of clothianidin such that suspension action is warranted under FIFRA.

The following sections address the specific claims in the petition.

B. *Correlating Bee Populations and the Registration of Clothianidin*

The petitioners claim that research indicates that honey bee colonies are in decline recently and that this decline appears to correlate with the registration of clothianidin and other neonicotinoid pesticides. The EPA agrees that the number of managed colonies in the United States has declined over time, but this decline cannot specifically be linked to the time period since the registration of the neonicotinoids. The neonicotinoids have only been registered for the last 20 years, but there has been a steady decline in managed colonies over the last 60 years.[3] This reduction is likely the result of numerous causes, including changing agricultural practices, changes in nutrition management, habitat loss, varroa mites, disease, climate, as well as other stressors. Given all these factors, simply noting that neonicotinoids have been registered during a period of pollinator decline is insufficient to show a connection with clothianidin and falls far short of what is needed to help support an imminent hazard finding. It must also be noted that, in the U.S., recent information suggests that colony losses in the last year were significantly less than in previous years despite the continued, consistent use of neonicotinoids[4]. While the EPA does not suggest that this information removes from doubt the possibility that neonicotinoids are causing harm to bees, it further supports the EPA's assessment that there is no clear correlation between the registration of clothianidin and declining bee populations.

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[3] vanEngelsdorp and Meixner. 2010. A historical review of managed honey bee populations in Europe and the United States and the factors that may affect them. Journal of Invertebrate Pathology. 103: S80—S95.

[4] Dennis vanEngelsdorp, Jeffery Pettis, Karen Rennich, Robyn Rose, Dewey Caron, Keith S. Delaplane, James T. Wilkes, Eugene J. Lengerich, Kathy Baylis, and the Bee Informed Partnership. Preliminary Results: Honey Bee Colony Losses in the U.S., Winter 2011-2012. http://beeinformed.org/2012/05/winter2012/. Accessed on 21 June 2012.

C. *Exposure to Clothianidin and Harm to Bees*

The petitioners allege that the weight of the science on both neonicotinoids generally and clothianidin in particular shows that exposure to harmful amounts of clothianidin is a likely factor in the abnormal decline of honey bees.

The open literature studies cited by the petitioners represent a broad array of methods and measurement endpoints. Many of the methods used in the laboratory and field studies cited involved novel approaches that did not account for potential confounding effects. In addition, the vast majority of the biological effects data cited by the petitioner were studies conducted on imidacloprid, a related, but different chemical than clothianidin. There is some uncertainty with associating endpoints from these studies, especially for chronic sub-lethal effects with equivalent doses of clothianidin. Additional studies conducted on other chemicals, such as pyrethroids, acaricides or cyano-substituted neonicotinoids, introduce further uncertainty. Also, many of the measurement endpoints reported in the studies involved sublethal effects to individual bees and for which there were no clear linkages with assessment endpoints of impaired survival, growth or reproduction at the level of the whole colony. As such, the EPA considers the utility of the studies in terms of their ability to either qualitatively or quantitatively define a predictive causal relationship between clothianidin and the individual honeybee or, more importantly, the bee colony, to be low. These studies are discussed in more detail in the Technical Support Document.

(1) Clothianidin Use and Presence in the Environment

The petitioners allege that circumstances giving rise to high clothianidin exposures are widespread because the pesticide is very widely used and persistent; dusts from seed treatments can expose bees regularly to harmful amounts of clothianidin; and given the systemic nature of clothianidin, bees are also regularly exposed to clothianidin residues in contaminated pollen, nectar and guttation water from visiting plants and trees. Guttation water is fluid that is exuded from the tips or edges of leaves of some plants.

The EPA agrees with the petitioners' claim that clothianidin use is widespread and common. For example, as of 2010, close to 90% of the total corn acreage planted in the U.S. is planted with corn seed that has been treated with nitroguanidine neonicotinoid pesticides (i.e., clothianidin, thiamethoxam, imidacloprid, and dinotefuran). Clothianidin is the primary neonicotinoid seed treatment used for corn, and is also approved for foliar and other uses on many crops and use sites.

The EPA also generally agrees with the petitioners' characterization of clothianidin as persistent. Clothianidin is stable across a wide range of soil conditions and in aquatic environments under conditions of reduced or low sunlight. However, while clothianidin residues may be found in soil for more than a year following the planting of treated seed, the EPA has no evidence that residues accumulate over multiple years of use. The registrant is currently conducting studies in California, requested by the California DPR[5], that examine residues in soils and plants after multiple-year applications to determine if the residues accumulate in the pollen and nectar[6]. Presence and build up in

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[5] http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/datareqproposal.pdf
http://www.cdpr.ca.gov/docs/registration/reevaluation/example_letter.pdf

[6] Beedle E.C. and A.M. Harbin. 2011. Determination of the Residues of Imidacloprid and its Metabolites 5-Hydroxy Imidacloprid and Imidacloprid Olefin in Bee Relevant Matrices Collected from Cotton, Grown at Locations Treated with Imidacloprid at Least Once Per Year During Two Successive Years. Study Number EBNTLO56-01. Unpublished study

soil of a systemic could lead to increasingly higher exposures over time. However the data seen to date do not suggest this is happening. The preliminary results of these studies do not demonstrate a significant cumulative effect of successive treatment years on residues in pollen or nectar.

(2) *Exposure Levels and Harm*

The petitioners assert that, given the widespread use and systemic nature of the pesticide, bees are regularly exposed to clothianidin through contaminated pollen and nectar from their foraging activity on plants and trees. The petitioners assert that these exposures can and do cause harm because clothianidin (1) has lethal effects on honey bees; (2) affects honey bee behavior and cognition in ways that compromise the overall health of colonies, consistent with the sorts of effects that may give rise to CCD; and (3) has interactive/synergistic effects with pathogens and disrupts bees' microbial communities.

(i) Lethal Effects to Bees

The EPA agrees that the data provided in support of the petition demonstrate that clothianidin is acutely toxic to bees, as is the case for many insecticides. But the critical question for this response is whether clothianidin is generally available in the environment at levels that can cause serious, imminent harm to bee populations. The EPA has reviewed the information provided, and there are data supporting the presence of clothianidin and other neonicotinoid insecticides in plant tissues including pollen, nectar and guttation water on plants grown from clothianidin-treated seed. The levels of clothianidin in pollen and nectar typically seen in the field are, however, generally below the levels at which sublethal effects reportedly happen, and lethal effects occur. Thus, the data do not suggest that bees are being regularly exposed to levels of clothianidin in pollen and nectar that could result in the sort of imminent, population level impacts necessary to support an imminent hazard finding. There is less certainty with respect to risk from guttation water. Levels of clothianidin in guttation water can be at levels toxic to bees immediately after seedling emergence, but appear to decrease rapidly, though are still at detectable levels up to three weeks following seedling emergence. The petition is not, however, supported by any information addressing the likelihood that a meaningful number of bees are likely to be present when guttation water is produced by seedlings, nor does the petition address when guttation water is likely to be available to bees, and whether or not the bees will use guttation water as a source of drinking water or as a means to cool the colony. Absent such information, there is no basis for determining the significance of this information and whether it supports petitioners' assertion that widespread exposures to bees are occurring at harmful levels. (The effects on bees of exposure to clothianidin residues in dust generated during the planting of treated seeds are addressed in section III.D of this response.)

(ii) Colony Collapse Disorder (CCD)

In addition to claims of lethal effects to bees, the petitioners assert that the use of clothianidin affects the behavior and cognition of bees in ways that compromise overall health of colonies (i.e., effects that allegedly may lead to CCD). CCD is characterized by the complete loss of adult forage bees without any signs of bee mortality leaving colonies with ample brood and food reserves along with a small cluster of hive-bees including the queen. The cited studies and available data appear to show in a laboratory setting evidence that imidacloprid, another neonicotinoid pesticide, can have sub-lethal effects on honey bees including effects on mobility, feeding activity and memory and associative learning capabilities. However, the studies cited do not address whether these effects are permanent or transitory or whether such effects would be likely for other neonicotinoid insecticides. Additionally, the

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prepared by Bayer CropScience. 148 p.

petitioners did not provide any evidence that the laboratory results are reflective of what would occur in the field and if so, whether the degree to which they occur would affect populations of honey bees. For example, the minimum concentrations at which significant biological effects occurred in the majority of the cited studies are not typically present in the field or in chronic concentrations present in nectar and pollen from the most widespread use patterns of clothianidin. In addition, the pesticide residue analyses from national surveys of commercial honey bee colonies indicate that colonies that were eventually determined to have succumbed to CCD did not contain elevated levels of neonicotinoids including clothianidin, nor do colonies in the areas of the U.S. where the most treated corn seed is planted appear to succumb to CCD at a higher rate than other colonies. Finally, any effects that we have seen in the field as a result of clothianidin uses, the incidents discussed in section D below, do not correspond with the characteristics of CCD. Thus, at this time, the agency is not aware of any data that demonstrate exposure to clothianidin results in effects on honey bee colonies consistent with those associated with CCD.

(iii) Synergistic Effects: Pathogens and Other Pesticides

The petitioners claim that clothianidin has interactive/synergistic effects with pathogens (such as *Nosema*) and with other pesticides that may be used concurrently with clothianidin. The EPA reviewed the cited literature and agrees that these studies indicate that concurrent exposure to insecticides at sublethal levels is associated with some increased sensitivity to *Nosema* infestations. The studies cited by the petitioners report this effect for imidacloprid, thiacloprid and fipronil. The EPA is uncertain about how to interpret these data. This research may apply only to the tested pesticides, or it may apply to other pesticides in the same chemical classes as the tested compounds, or it may indicate that exposure to many different classes of insecticides, not just neonicotinoids, can contribute to increased sensitivity to pathogens. However, these studies do not show a dose-response effect and the effects observed seem to be limited to individual bees, not entire colonies. Furthermore, these effects were typically seen at concentrations above those that would be expected in the environment or would be likely to be observed in pollen and nectar from the most widespread use patterns for clothianidin and other neonicotinoids. The petitioners did not provide any evidence to show that clothianidin, specifically, would result in a similar weakening of the honey bee and increased susceptibility to disease.

Despite the petitioners' allegations that clothianidin disrupts bees' microbial communities (i.e., natural, symbiotic microbial cultures within the bee gut and throughout the hive), they did not cite studies to defend their assertion regarding a negative effect of neonicotinoid pesticides in general, and clothianidin in particular, on the microbial community of the honey bee.

D. *Incidents*

The petitioners allege that adverse incidents reports provide additional support for the conclusion that clothianidin is causing widespread harm to bees. Historically in the U.S., however, despite the widespread use of clothianidin, only a handful of incidents have been reported to the EPA and, in those cases, the role of clothianidin was not definitively established. Clothianidin has been registered for 9 years, use has been increasing during that time, and the EPA has until this year received in its Ecological Incident Information System (EIIS) only a total of 6 incidents that specifically mention clothianidin involving the loss of bees. We are, however, aware of 14 additional incidents occurring in the U.S. in 2012 that are not yet present in the database and approximately 120 additional incidents reported in Canada. All of these incidents are under investigation and the causes have not yet been conclusively established. The EPA's preliminary analysis indicates that most of these incidents are associated with the planting of corn seeds treated with a neonicotinoid pesticide. The majority of these recent incident reports indicate that there were unusual conditions – dry, windy conditions in the Midwest and Canada

that promoted the movement of dusts from seed treatment – and that bees were foraging in fields at the same time due to unusually warm conditions for the time of year. These incident reports indicated that while dead or dying bees were observed at the entrances to the beehives, entire colonies were not lost. In addition, these incidents are not consistent with CCD, in that CCD is characterized by the complete loss of adult forage bees without any signs of bee mortality.

A bee kill incident in Germany in 2008 and an incident in Slovenia in 2011 are the only two large incidents (>1000 colonies affected) that the agency is aware of which have been definitively associated with clothianidin seed treatments. In both cases, the incidents resulted from the planting of clothianidin-treated corn seed during unusual dry, windy conditions where abraded seed coatings drifted to adjacent fields that were in full bloom and where bees were actively foraging. There may also have been issues with regards to sticking agents not being used according to standard industry practices. According to reports of the German incident, which appears to be the most serious incident to date, some colonies showed only minor bee losses and only a slightly enhanced mortality, while other colonies showed severe damages; the scale of impact of the poisoning of colonies damaged varied between 10 – 90%. Loss of entire colonies was reported in only a few cases.

While the recent incidents bear further study and will continue to be evaluated as we respond fully to the petition and complete the registration review of clothianidin, the information available on incidents does not indicate that clothianidin use is resulting in the loss of large numbers of honey bee colonies across the U.S. The available information instead seems to indicate that the seed treatment use pattern may result in some sporadic incidents affecting individual bees (in some cases, many bees), but there has not been widespread colony or population losses that would indicate the potential for serious harm. Given the widespread planting of clothianidin- and thiamethoxam[7]-treated corn seed, if clothianidin were causing serious harm, the EPA would expect to see far more incident reports indicating more frequent mass deaths of honey bees than it has historically received.

The EPA anticipates that investigation of the recent U.S. incident data may help to inform future risk assessments and regulatory decisions and will allow the EPA to identify measures to mitigate acute exposures of bees and other pollinators to abraded dust from clothianidin seed treatments.

E. *Agricultural Losses and Ecological Impacts*

The petitioners do not cite and we are not aware of any evidence of agricultural decline or declines in honey production as a result of losses to pollinators, nor do the petitioners provide evidence of imminent ecological damage. The EPA sees no evidence that clothianidin is having the sort of harm asserted by petitioners or that it is likely to have such harm in the near future such that it presents an imminent hazard.

IV. Conclusion

Based on the analysis described above, the EPA denies your request to suspend clothianidin on the basis of the information currently available to the agency and reviewed in responding to the imminent hazard claims. In order to suspend the registration of a pesticide under FIFRA, the EPA must find that an "imminent hazard" exists. The federal courts have ruled that to make this finding, the EPA must conclude, among other things, that there is a substantial likelihood that imminent, serious harm will be experienced from the use of the pesticide. While the information before the EPA, including the information you provided to us, clearly indicates that clothianidin is acutely toxic to bees, your request

[7] Thiamethoxam, another neonicotinoid insecticide, degrades to clothianidin.

for suspension does not demonstrate a causal link between clothianidin and harm to bees sufficient to justify the suspension of these pesticides under the FIFRA imminent hazard standard. The petition cites no data demonstrating population-level effects from the use of clothianidin in real-world situations that could have widespread effects on agriculture or ecosystem level impacts, and the EPA is aware of no other evidence that suggests the existence of these sorts of impacts. The petition therefore does not establish that serious, imminent harm is occurring or will likely soon occur from the continued use of clothianidin.

Although the EPA finds that the imminent hazard arguments in the petition are facially inadequate and warrants denial of the petition for that reason, the agency analyzed each claim against the factors for relief under the imminent hazard standard and comes to the following conclusion. The EPA distilled the petitioners' claims addressed above into three areas: (1) honey bee populations are in decline and the decline is correlated to the registration of clothianidin and other neonicotinoid pesticides; (2) harmful exposures to clothianidin and other neonicotinoids are a likely factor in the decline of honey bees; and (3) the decline of honey bee populations due to clothianidin will result in losses in the tens of billions of dollars. As described below, the EPA finds that none of these claims meets any of the following criteria for a finding of an imminent hazard.

(1) Seriousness of the threatened harm

Petitioners failed to provide adequate evidence to show that there is a serious threatened harm to honey bees from the use of clothianidin. In the context of risks to honey bees, the EPA believes a serious harm would exist if the pesticide is causing population or colony losses that result in significant ecological or economic damage. Although clothianidin is known to cause acute effects, there is no evidence that bees are being exposed to levels of this pesticide that would cause the population effects alleged by the petitioners.

(2) Immediacy of the threatened harm

As the EPA stated under the first factor, the petitioners failed to provide evidence that a serious threatened harm exists. Additionally, even if there was a serious threatened harm, as noted above the petitioners failed to provide evidence that it is imminent within the meaning of the FIFRA suspension standard – that is, likely to occur in the 1 to 2 year period necessary to complete a cancellation proceeding. The EPA believes a good indicator for immediacy is the nature and extent of reported incidents. The EPA has received very few incident reports related to clothianidin use and most of the incidents reported do not rise to the level of an immediate serious threatened harm. The EPA would expect to see many more widespread incidents if there was an immediate serious threatened harm to honey bees. Additionally, the studies cited by the petitioners do not support this finding. Further, separate and apart from incident reports and research, the petition does not identify, and the EPA is not aware of, any significant agricultural losses or reductions in honey production that would suggest that serious harm is occurring or likely to occur within the next year or two.

(3) Probability that the threatened harm will occur

Following on the previous discussions on the first two factors, petitioners failed to provide evidence to show that there is a substantial likelihood that the alleged threatened harm will occur. As noted, clothianidin has been registered for 9 years and the EPA has received only a limited number of incidents related to the use of this pesticide in the U.S. In the EIIS, the EPA has received only a total of 6 incidents involving the loss of bees. We are aware of 14 additional incidents occurring in the U.S. in 2012 that are not yet present in the database and approximately 120 additional incidents in Canada. As

noted above, all of these incidents are under investigation and the causes have not yet been conclusively established. As stated by the petitioners, the use of clothianidin is widespread; therefore the EPA would expect to see more pervasive incidents to evidence that there is a substantial likelihood that there is a serious harm to honey bees from the use of the pesticide. There remains some degree of uncertainty as to whether reported incidents are properly capturing the full extent of the risk. The EPA agrees with the scientific community that additional research is necessary to address CCD. However, the existence of uncertainty as to these questions is not sufficient to satisfy the high probability standard necessary to support a finding of imminent hazard. Accordingly, neither the information provided to support the claims, nor information in the agency's files (including incident data) indicates that there is a substantial likelihood that the use of clothianidin will cause a serious, imminent harm.

(4) Benefits to the public of the continued use of the pesticide

Because the EPA has not found that imminent, serious harm is substantially likely, the agency has not performed a new benefits analysis in relation to this petition and relies instead on earlier assessments regarding the benefits of clothianidin. As noted, petitioners failed to include consideration of this or any other benefits information in requesting that the EPA suspend clothianidin based on the presence of an imminent hazard.

In closing, let me assure you that the EPA shares your concerns about the potential effects on bees and other pollinators from exposure to pesticides and, as explained above, the EPA is working closely with our partners to examine the effects of pesticides on bees and other pollinators. Once the public comments to the remaining portions of the petition have been received and reviewed, the EPA will respond to the remainder of your petition. In addition, the EPA will determine in connection with that review whether the recently submitted supplemental materials and comments received support the reconsideration of this partial response.

Steven P. Bradbury, Ph.D.
Director, Office of Pesticide Programs

Attachment: Technical Support Document